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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,344	09/10/2004	Lauretta Maggi	28069-602 NATL	3801
30623	7590	03/18/2010	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C			AHMED, HASAN SYED	
ONE FINANCIAL CENTER				
BOSTON, MA 02111			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			03/18/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,344	<b>Applicant(s)</b> MAGGI ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/17/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicants': (a) amendment and remarks, filed on 4 December 2009; and (b) IDS, filed on 17 November 2009.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-27 remain rejected and new claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 5,487,901 ("Conte") in view of U.S. 6,599,284 ("Faour").

Conte discloses a pharmaceutical tablet composed of an upper layer containing active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being almost completely coated with an insoluble polymeric coating (col. 2, lines 30-45). The tablet is completely coated with an impermeable polymeric film (col. 2, lines 52-53). The upper layer also comprises polymeric excipients (col. 4, lines 1-9). The amount of the excipient with respect to the total weight of the tablet is 1-90% by wt (col. 4, lines 10-13). The upper layer is 0.5-5 mm thick (col. 4, line 39). The intermediate layer is made of gelable or erodible

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polymers (col. 4, lines 40-53). The amount of polymeric substance in respect of the total weight of the tablet is 5-90% (col. 4, lines 55). The intermediate layer is 0.1-4.5 mm thick (col. 5, lines 31). The third layer has the same composition as the upper layer (col. 5, lines 32-36). The lower layer is 0.5-5 mm thick (col. 5, line 37). The tablet is coated with an impermeable polymeric material that is insoluble or exhibits delayed solubility, or a solubility that is pH dependent (col. 5, lines 40-46). The polymeric coating in respect of the finished tablet is 0.2-20% by wt (col. 5, lines 54-55). The upper layer is partially exposed to the environmental fluid because a raised portion was removed after final coating with impermeable polymeric coating (col. 2, lines 54-55).

Conte explains that the disclosed formulation is beneficial in allowing for an immediate release of active ingredient followed by a later delayed release (col. 2, lines 30-47).

Conte differs from the instant application in that it does not disclose a laser incision.

Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredient (2), an intermediate layer forming a semipermeable membrane (3), and an inner layer or core containing active ingredient (4) (Figure 4). The dosage form also comprises a passageway (5) formed by laser incision (col. 13, lines 48-55), which is incised in correspondence with both the first and third layer (Figure 4). The reference also teaches the addition of osmopolymers (col. 16, lines 1-45), and disintegrating agents (col. 18, lines 25-38). The reference further discloses that the outer layer or external coating layer may contain the same or different

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active ingredients as the inner layer (col. 13, lines 5-7). Example 1 discloses the composition of the inner core, which comprises more than 49% by wt polymeric material (col. 24, lines 15-25). Example 1 also discloses the use 5% by wt of polyethylene glycol (col. 24, lines 25-30). Faour incorporated by reference Theeuwes et al. US 4088864, which discloses the laser source as CO<sub>2</sub> and the output of 20W. Therefore the process claims are also anticipated by this reference.

With respect to new claim 28, Faour teaches that the passageway or passageway precursor (see col. 11, line 59) can be formed optionally after the external coat is applied to the semipermeable membrane of the osmotic device (see col. 8, line 30; fig. 4). The external coat may be comprised of polymeric materials (see col. 13, lines 5-28). The laser formed passageway or passageway precursor may take the form of different sizes and shapes (see col. 14, lines 18-19). In one embodiment, the passageway or passageway precursor is scored onto the coating (see col. 14, lines 22-26 and lines 30-32; fig. 7(13), 7(15), and 7(19)). When the coating is scored or etched, the coating ruptures during use (see col. 14, lines 24, 29, and 40); i.e. the coating remains intact until it is employed for its intended use - eroding in gastric fluids.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a tablet system comprising two external layers and a third internal layer with laser incisions on the surface, as taught by Conte in view of Faour. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a tablet because it is useful in providing an immediate

release of active ingredient, followed by a delayed release, as explained by Conte (see above).

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed on 4 December 2009 have been fully considered but they are not persuasive.

1. Applicants argue that Faour does not generate one or more laser incisions delimiting an area of the polymeric material of a geometric shape and predetermined dimensions. See remarks, pages 11 and 12.

Examiner respectfully disagrees. As explained in the substantive rejection, above, Faour teaches that the passageway or passageway precursor (see col. 11, line 59) can be formed optionally after the external coat is applied to the semipermeable membrane of the osmotic device (see col. 8, line 30; fig. 4). The external coat may be comprised of polymeric materials (see col. 13, lines 5-28). The laser formed passageway or passageway precursor may take the form of different sizes and shapes (see col. 14, lines 18-19). In one embodiment, the passageway or passageway precursor is scored onto the coating (see col. 14, lines 22-26 and lines 30-32; fig. 7(13), 7(15), and 7(19)). The laser incision can delimit an area of geometric shape and predetermined dimensions (see, e.g., fig. 7(15)).

2. Applicants argue that the unexpected results are based on increased stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration of the formulation. See remarks, pages 11 and 12.

Examiner respectfully submits that Faour also teaches an embodiment wherein laser etching or scoring of the coating keeps the etched or scored portion of the coating intact (i.e. the etched or scored portion of the coating will not be removed) until it is in use (see col. 14, lines 24, 29, and 40; fig. 7(13), 7(15), and 7(19)).

3. Applicants argue that Conte and Faour cannot be combined because Conte teaches a formulation where a portion of the coating is removed only when the tablet is exposed to an aqueous environment upon administration, while Faour discloses an osmotic device with a core that is surrounded by a semipermeable membrane with a passageway that delivers the active agent to an environment of use in a controlled manner. See remarks, paragraph bridging pages 12 and 13.

Examiner respectfully submits that like Conte, Faour also teaches an embodiment wherein a portion of the coating is removed only when the tablet is exposed to an aqueous environment upon administration. As explained in the substantive rejection, above, the passageway or passageway precursor taught by Faour is scored onto the coating (see col. 14, lines 22-26 and lines 30-32; fig. 7(13), 7(15), and 7(19)). When the coating is scored or etched, the coating ruptures during use (see col. 14, lines 24, 29, and 40); i.e. the coating remains intact until it is employed for its intended use - eroding in gastric fluids. As such, examiner respectfully submits that Conte and Faour are properly combined.

\* \* \* \* \*

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1615

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1615